# Endovascular suture versus cutdown for endovascular aneurysm repair: A prospective randomized pilot study

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***Purpose:*** **To evaluate safety and cost benefits of the percutaneous technique for treatment of aortic aneurysm, a prospective randomized study was performed that compared the endovascular suture technique with conventional cutdown access and repair.**

***Materials and Methods:*** **From January 2002 through July 2002, 30 endografts, including 14 Talent stent-grafts (Medtronic, Sunrise, Fla) and 16 Zenith endografts (Cook, Bloomington, Ind) were implanted in 30 patients for endovascular aneurysm treatment. The patients were randomized to either percutaneous technique (group A) or conventional cutdown (group B). Fifty-five femoral arteries were cannulated with large-bore (14F-25F) introducers and were included in the study. Safety and efficiency of both techniques were assessed by recording the complication rates, operation time, discharge, and time to ambulation. Comparison of selected estimated costs included both variable and fixed costs for femoral access and expenses for treatment of complications.**

***Results:*** **No operative deaths occurred. The complication rates were similar and included 1 arterial thrombosis in each group, 3 lymphoceles in group B, and 1 conversion to cutdown because of bleeding in group A. Mean surgery time (86.7 ± 27 minutes vs 107.8 ± 38.5 minutes; $P < .05$) and time to ambulation (20.1 ± 4.3 hours vs 33.1 ± 18.4 hours; $P < .001$) were significantly shorter in the group treated percutaneously. Because of the cost of the closure device, total cost of the percutaneous technique averaged 99.2 € more than cutdown.**

***Conclusions:*** **The percutaneous technique decreases the invasiveness of endovascular therapy of aortic aneurysm and reduces operative time and time to ambulation. Complications were roughly equivalent in severity. The additional cost for the device appears to justify its use for this form of aneurysm treatment. (J Vasc Surg 2003;38:78-82.)**

Access to the femoral artery during endovascular aneurysm repair is commonly achieved with open femoral incision. With endovascular suture devices and the "pre-close" application technique, it is possible to repair aortic aneurysms totally percutaneously.[1-4] Even with large-bore (up to 27F) introducer sheaths, aortic aneurysms can be treated without surgical cutdown of the femoral arteries.[5] Both surgical dissection and percutaneous vascular suturing have associated morbidity. Paresthesia, lymphoceles, and healing disorders are frequent complications of wounds in the groin. The scars make repeat interventions to treat endoleak or graft occlusion more difficult. On the other hand, false aneurysm and arterial thrombosis are typical complications of percutaneous techniques.[6]

Until now, no randomized studies have been published comparing the two techniques for treatment of aortic aneurysm. Therefore we undertook a prospective randomized trial to compare the efficacy and safety of totally percutaneous access and surgical exposure of the femoral artery in patients undergoing endovascular aneurysm repair.

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## METHODS

Between January and July 2002, 30 consecutive patients (29 men) with mean age of 72.9 ± 9.9 years (range, 51-90 years) underwent endovascular repair of an aneurysm of the abdominal aorta (n = 28) or thoracic aorta (n = 2). The patients were randomized to either percutaneous technique (n = 15; group A) or surgical cutdown (n = 15; group B) for femoral access of sheaths 14F or larger. The study protocol was approved by the human ethics committee of our institution. Written and oral consent was obtained from the patients before inclusion in the trial. All patients were considered candidates for the study, including those with calcification of the femoral artery, scar in the groin, or obesity. Exclusion criteria (psychiatric patients, patients undergoing implantation of an aortomonoiliac endograft, patients with an aneurysm of the femoral artery) were set, but no patients with these characteristics were treated during the study period. Twenty-eight procedures were performed after administration of spinal anesthesia, and 2 were performed with the patient under general anesthesia. Sixteen aneurysms were excluded with the Zenith graft (Cook, Bloomington, Ind), and 14 with the Talent endovascular graft (Medtronic, Sunrise, Fla). All procedures were performed by four experienced vascular surgeons. All investigators had performed more than 30

endovascular sutures with Prostar XL before the start of the study.

Fifty-five femoral arteries (27 in group A, 28 in group B) cannulated with a sheath 14F or larger were considered for the study (Table I). In 5 cases a straight aortic graft was implanted without the necessity of using a large-bore introducer for the contralateral leg. Since conventional compression techniques for the contralateral approach were used in these cases, 5 femoral arteries were not included in the study.

In group A (percutaneous technique) one 10F Prostar XL percutaneous vascular surgery device (Perclose, Redwood City, Calif) was used in the "pre-close" technique for closure of the access site, as described.[1-4,7]

According to this technique, deployment of the suture is performed at the beginning of the procedure, ensuring that the needles penetrates the arterial wall before the arteriotomy is enlarged by introduction of sheaths larger than 10F.

Arterial access was achieved with an 18-gauge needle by introducing an 8F sheath. Over a 0.035 inch nonhydrophilic guide wire, the sheath was exchanged for a 10F Prostar XL. After removing the Prostar catheter and before introduction of the graft, a 12F or 14F sheath for dilation of the vessel at the access site was inserted. The endograft was then implanted as usual, after removal of the 14F sheath over a Lunderqvist guide wire with manual compression of the groin.

In the patients randomized to surgical cutdown (group B) a transverse groin incision was made, to expose the common femoral artery for direct needle puncture. Proximal and distal control of the vessel was obtained with vessel loops and vascular clamps. After the sheath was removed, the artery was repaired with fine polypropylene sutures. Vacuum drains were placed in the incision, which was closed in layers.

All patients received a bolus of 5000 IU of heparin after sheath insertion. No protamine was given at the end of the procedure. Duplex ultrasound scanning of the groin was performed before and after the operation. Preoperative computed tomography included imaging of the groin to assess calcifications or aneurysm of the common femoral artery. Decreases in hemoglobin and hematocrit were used as an indicator of blood loss. Both parameters were measured 1 day before and 1 day after the procedure. Efficiency and safety were measured by surgery time and time to ambulation, as well as by frequency of local complications (Table II). Total duration of the procedure and hospital costs for vascular access and surgical treatment of groin complications were calculated by the hospital administration and expressed in euros (in July 2002, 1 US dollar equaled approximately 1 euro).

The difference in hospital costs between the two techniques was estimated in terms of the variable costs (Prostar device and instrumentation costs for cutdown) and fixed costs (costs for surgery and anesthesia per minute). Operation time in minutes ("skin-to-skin") was multiplied by the average surgeon (0.96 €/min), anesthesiologist (0.85 €/min), and nurse (0.40 €/min) salary. Costs assumed to be the same for both procedures (eg, basic instrumentation, diagnostic evaluation, grafts and catheters, patient medication, recovery room) were not considered in this partial comparison of estimated costs.

**Table I.** Patient characteristics and graft data

| | *Percutaneous procedure* | *Cutdown procedure* |
|---|---|---|
| Patients | 15 | 15 |
| Age (y) | 74.5 ± 10.4 | 71 ± 9.6 |
| Obesity | 6 | 7 |
| Main body (mm) | 29.2 ± 3.8 | 29.6 ± 4 |
| Contralateral leg (mm) | 15.4 ± 3.4 | 15.1 ± 2.1 |
| Talent stent-graft | 9 | 5 |
| Zenith stent-graft | 6 | 10 |
| Sutured arteries | 27 | 28 |
| 14F sheath | 4 | 8 |
| 16F sheath | 3 | 2 |
| 18F sheath | 9 | 5 |
| 20F sheath | 4 | 8 |
| 22F sheath | 1 | 3 |
| 24F sheath | 6 | 1 |
| 25F sheath | 0 | 1 |
| Sheath (mean diameter) | 19 ± 3.4 | 18.2 ± 3.3 |

Values represent number or mean ± SD.

The Mann-Whitney *U* test was used for comparison of nonparametric variables. Complications were analyzed with the Fisher exact test.

Categorical variables are expressed as frequency and percentage, whereas continuous variables are presented as mean ± SD. Differences were considered significant at $P < .05$.

## RESULTS

Of the 30 patients enrolled in the study, 15 were randomized to receive percutaneous treatment (group A) and 15 to undergo the cutdown procedure (group B). In all patients, endovascular treatment was successfully performed, with no in-hospital deaths. Analysis of basic patient characteristics (gender, age, obesity) and of the data for the graft used (type, diameter of both graft and introducer sheath) showed no significant differences between groups (Table I). As evidence of successful randomization, no significant differences were found in fluoroscopy time (17.4 ± 6.6 minutes in group A vs 19 ± 15.1 in group B).

In 1 patient (3.7%) the Prostar device was unsuccessful in closing the arterial entry site, and conversion to an open groin incision was necessary. Since the guide wire was previously removed, temporary hemostasis could not be achieved with a balloon catheter. Applying gentle compression above the inguinal ligament, the bleeding was treated with arterial suturing. For better identification of the leak, the endovascular suture was left in place.

In all patients in group A, only one Prostar device was used. In 3 patients device failure was observed, caused by deflection of needles through a calcified femoral artery in 1 patient and failure of the needles to grasp the arterial wall in

**Table II.** Efficiency and safety parameters

| | *Percutaneous procedure* | *Cutdown procedure* | P |
|---|---|---|---|
| Surgery time (min) | 86.7 ± 27 | 107.8 ± 38.5 | <.05 |
| Fluoroscopy time (min) | 17.4 ± 6.6 | 19 ± 15.1 | NS |
| Time to ambulation (hr) | 20.1 ± 4.3 | 33.1 ± 19.4 | <.001 |
| Hemoglobin loss (g/100 mL) | 2.0 ± 0.7 | 2.2 ± 0.9 | NS |
| Hematocrit loss (%) | 6.0 ± 2.5 | 6.5 ± 2.1 | NS |
| Arterial thrombosis | 1 | 1 | NS |
| Primary hemostasis | 26/27 | 28/28 | NS |
| Need for vascular repair | 2 | 1 | NS |
| Pseudoaneurysm/blood transfusion | 0 | 0 | — |
| Paresthesia/infection | 0 | 0 | — |
| Lymphocele | 0 | 3 | NS |
| Mean access material cost (Euro) | 223.6 ± 63.8 | 18 ± 0 | <.001 |
| Mean OR usage cost (Euro) | 251.2 ± 89 | 357.6 ± 153.3 | <.01 |

Values represent numbers or mean ± SD.
*OR*, Operating room; *NS*, not significant.

**Table III.** Sheath diameter and success rate

| *Author* | *Sheath size (F)* | *Procedures (n)* | *Success rate (%)* |
|---|---|---|---|
| Howell et al[1] | 16 | 144 | 94.4 |
| Traul et al[3] | 16 | 14 | 71.4 |
| Traul et al[3] | 22 | 12 | 75 |
| Haas et al[7] | 16-22 | 13 | 100 |
| Teh et al[2] | 16-22 | 82 | 85 |
| Torsello et al[5] | 14-27 | 145 | 93.8 |
| Howell et al[11] | 16-22 | 60 | 96 |

2 obese patients. In all cases, a second device was used without late complications.

Distal embolization or dissection of the arterial wall was not observed during the study. Since the device is a monorail system, the wire was usually removed before the wire entry port passed under the skin. Because of tortuosity of the aorta in 2 patients, it was not possible to pass the J-loop tip of the catheter into the aorta after removing the wire. In these patients we left the wire in situ to prevent damage to the vessel wall or distal embolization.

Wound complications consisted of three lymphoceles (cutdown group), which did not require specific treatment and healed completely. Postoperative femoral occlusion developed in 1 patient in each group and was treated successfully with surgical thrombectomy.

Surgical repair of the access artery was necessary in 2 patients in group A, because of bleeding in 1 and arterial thrombosis in the other (13%), and in 1 patient in group B, because of arterial thrombosis (6.6%). The cause of femoral occlusion was intimal damage after clamping in 1 patient in group B and after mobilization of a calcified plaque inward by the large sheath in 1 patient in group A.

The percutaneous technique did not significantly reduce the amount of blood loss, although a trend toward decreased hemoglobin (10%) and hematocrit (8%) was noted in group A (Table II). Blood transfusion or surgical repair because of secondary hemorrhage was not necessary in either group. No pseudoaneurysm in either group was observed.

Mean operation time (107.8 ± 38.5 minutes vs 86.7 ± 27 minutes; $P < .05$) and time to ambulation (33.1 ± 19.4 hours vs 20.1 ± 4.3 hours; $P < .001$) were significantly longer in the conventional treatment (cutdown) group.

Cost of materials for femoral access in group A (Prostar device and treatment of complications) was significantly higher than in group B (223.6 ± 63.8 € vs 18.0 ± 0 €; $P < .001$), but the percutaneous technique significantly reduced hospital resource use (mean cost for use of operating room, 251.2 ± 89 € in group A vs 357.6 ± 153.3 €; $P < .01$) compared with the cutdown approach. Despite these differences, the combined additional cost averaged 99.2 € more in the percutaneous group, mainly because of the cost of the catheter itself (474.7 ± 109.7 € vs 375.5 ± 153.3 €; $P < .01$).

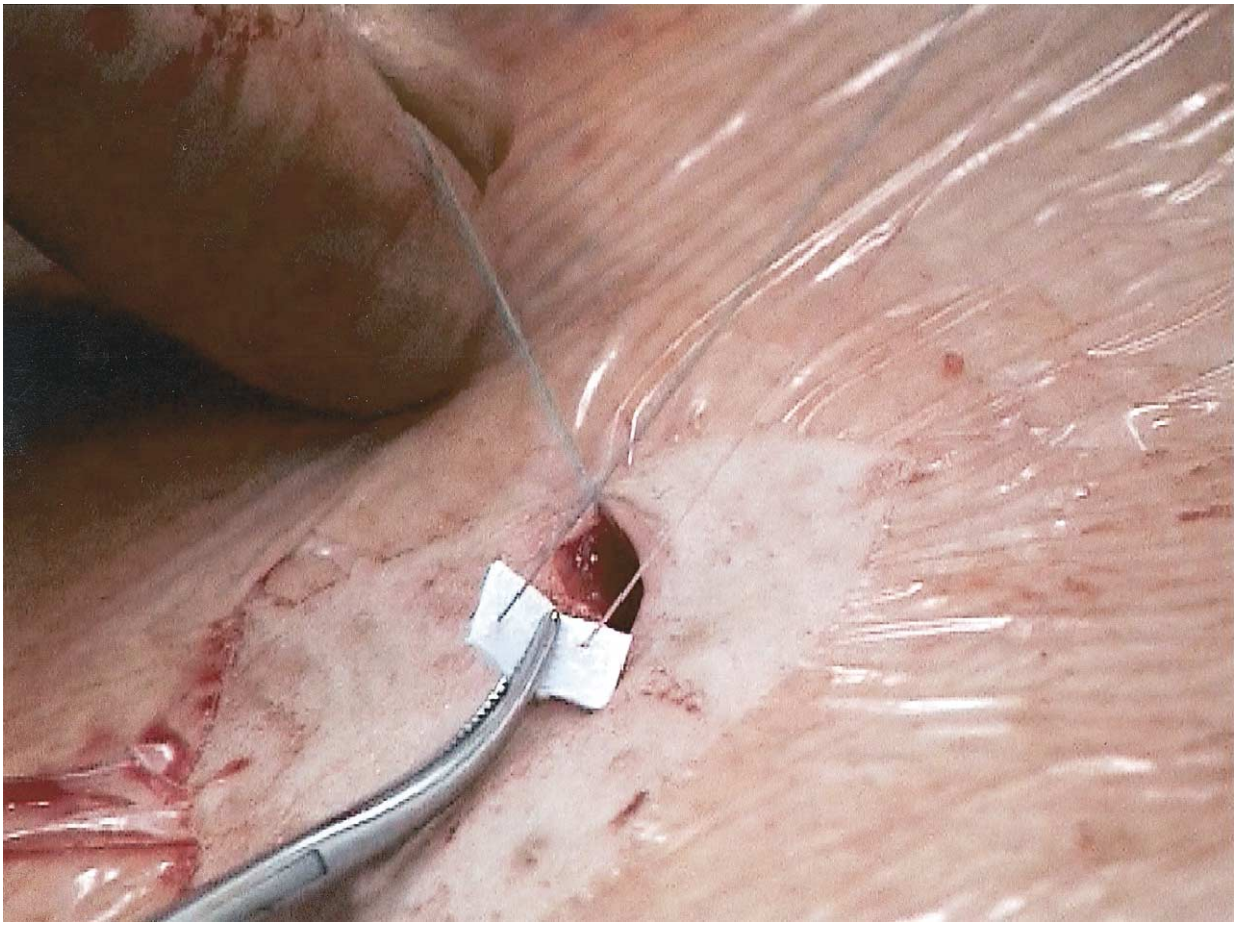
## DISCUSSION

Access to the femoral artery in the endovascular treatment of aortic aneurysm is commonly achieved with operative femoral cutdown. This minor surgical procedure is sometimes associated with postprocedural groin complications and patient discomfort.[8]

In addition, necessity for repeat intervention after endovascular aneurysm repair is high,[9] and the transfemoral approach is most frequently used. Avoidance of open femoral exposure can thus decrease risk for inguinal complications after repeat operations and femoral puncture in a scarred groin.

New technology allows arteriotomy repair with a percutaneous suture device even after use of large-bore introducers.[1-4,7,10] In an attempt to perform aneurysm repair without any open component, the feasibility of percutaneous access, also after using sheaths up to 27F, was analyzed in a nonrandomized study.[5]

The success rate with the percutaneous technique ranged between 71.4% and 96%, depending on patient



With the percutaneous technique, bleeding sometimes occurs from needle holes or from gaps between sutures. Minor bleeding can generally be stopped by using a knot pusher to ensure approximation of the knot to the arterial wall. If primary hemostasis cannot be obtained, a PTFE felt pledget can be used as a patch and sewn with the sutures of the Prostar device.

volume and selection (Table III). Obesity, calcified femoral arteries, scarred groin, and kinking of both iliac arteries and aorta were the main risk factors for failure of the device to close the arteriotomy,[2,3,5,6] requiring conversion to an open groin incision. In addition, patients with small and diseased femoral arteries are not good candidates for percutaneous vascular suturing after use of large-bore sheaths. Since abundant subcutaneous fat makes the advancement of the device difficult, obesity is also an important risk factor. Because of difficulty in creating an adequate subcutaneous tunnel for the hub of the device, the needles failed to grasp the arterial wall in 2 obese patients in this study. While testing the free run of the sutures, a tear in the vessel wall was detected. With the guide wire left in place, a second device was inserted, and the sutures were deployed successfully.

In 1 patient severe calcification of the femoral artery caused deflection of the nitinol needles, which did not enter the barrel of the device. Pushing the handle back into the hub of the device did not correct the problem; thus conversion to open incision was performed to remove the needles.

Factors leading to failure of the procedure are not only patient-related or device-related, but also depend on the expertise of the operating team. We found that the complication rate decreased with increasing experience with the device.[5] Since the suture material is multifilament polyester, it is important to irrigate the sutures well to ensure free knot slippage down to the arteriotomy.

Former experience with the use of two percutaneous closure devices showed that the presence of too many threads can cause catching on other sutures, disrupting the vessel wall during fastening of the knot. Use of only one device did not increase the rate of bleeding complications in this study.

Appropriate puncture and suture technique is mandatory. If the puncture is too caudal there is risk for introducing the large-bore sheath through the superficial femoral artery or through the profunda, increasing the risk for damage to the vessel.[5]

In cases of tortuous aorta or iliac artery, we introduce the Prostar catheter under fluoroscopic guidance to control the position of both the guide wire and the catheter to prevent dissection and distal embolization. If necessary, we do not remove the guide wire even after the wire entry port has passed under the skin. Angiography is recommended in patients in whom difficulties are encountered during placement of the closure device. In cases of leak due to tearing of sutures through a diseased arterial wall, we use manual compression or a polytetrafluoroethylene felt pledget patch attached with the four vascular sutures of the Prostar device (Figure).

In summary, endovascular suturing enables completely percutaneous repair of aortic aneurysm. After initial scepticism due to user and device failure, at our institution complete percutaneous repair has become the approach of first choice to treat aortic aneurysm in patients considered candidates for endovascular treatment. Arterial exposure (cutdown procedure) is used only in patients with occlusive or aneurysmal disease of the femoral artery or requiring aortomonoiliac grafting. The operative costs of the new technique are higher because of the purchase price of the device. Nevertheless, the procedure is less invasive, is time-saving, and may result in shorter convalescence after endovascular repair of aortic aneurysm.

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